

## **REMARKS**

This is a full and timely response to the Office Action of August 10, 2010. Reconsideration and allowance of the application and all presently pending claims are respectfully requested.

Upon entry of this Response, claims 1-48 are pending in this application. Claims 1 and 31 are currently amended. Claims 29-30 and 46-48 are withdrawn. The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

### **I. Claim Rejections – 35 U.S.C. § 103(a)**

Claims 1-28 and 31-45 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Phillips (U.S. 2002/0045646) in view of Bergstrand, et al. (U.S. Patent No. 5,817,338), in further view of Chen (U.S. 2001/0006649). Applicants respectfully traverse.

#### **A. Independent Claims 1 and 31 are Allowable over Phillips in view of Bergstrand, et al., in further view of Chen**

Independent claims 1 and 31 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Phillips (U.S. 2002/0045646) in view of Bergstrand, et al. (U.S. Patent No. 5,817,338), in further view of Chen (U.S. 2001/0006649). Applicants respectfully traverse.

Independent claim 1, as amended, recites as follows:

1. An oral pharmaceutical composition comprising **at least three separate and distinct populations** of at least one of beads, pellets, tablets and granules provided in a capsule, the **at least three separate and distinct populations** comprising:

(i) a first population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a first rate, wherein the first population is selected from the group consisting of: a population of beads, a

population of pellets, a population of tablets, a population of granules, and any combination thereof;

(ii) a second population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a second rate, wherein the second population is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof; and

(iii) a population of a basic substance, wherein the population of the basic substance excludes said pharmaceutical active substance, the population of the basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof.

(emphasis added).

Independent claim 31, as amended, recites as follows:

31. An oral pharmaceutical composition comprising **at least three separate and distinct populations** of at least one of beads, pellets, tablets and granules provided in a capsule, the **at least three separate and distinct populations** comprising:

(i) a population of a pharmaceutical active, wherein the population of the pharmaceutical active is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof;

(ii) a population of enteric coated pharmaceutical active, wherein the population of enteric coated pharmaceutical active is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof;

(iii) a population of a basic substance, wherein the population of the basic substance excludes said pharmaceutical active, the population of the basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof; and

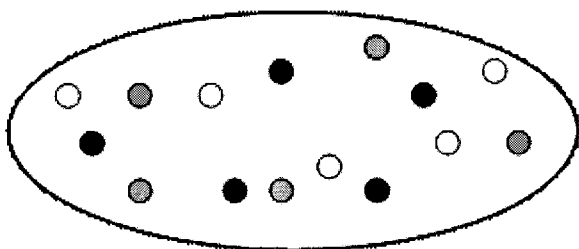
(iv) a population of enteric coated basic substance, wherein the population of enteric coated basic substance excludes said pharmaceutical active, the population of enteric coated basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof.

(emphasis added).

Applicants note that support for the amendments to claims 1 and 31 may be found in the description at, for example, page 8, line 21 to page 9, line 11; page 11, lines 10-32; and the Examples.

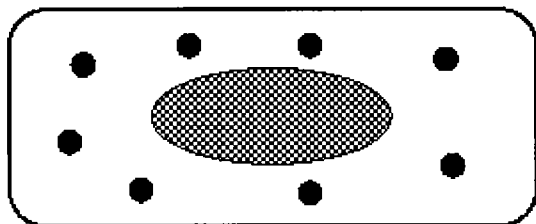
Applicants submit that the independent claims explicitly state that the composition comprises at least three "separate and distinct" populations, the populations being (i), (ii), and (iii), and being provided in a capsule, as recited in the claims. This is not taught or suggested by the cited references, alone or in combination.

The present disclosure is directed to a capsule comprising three separate and distinct populations, a first population comprising an active agent releasable at a first rate, a second population comprising an active agent releasable at a second rate, and a third population being a basic substance, wherein the population of basic substance excludes the active agent. Each of the populations is independently formulated as beads, pellets, tablets, or granules. Since the term "population" is used in addition to the recitation of the beads, pellets, tablets, or granules in plural form, it is evident that the claimed invention comprises a capsule filled with more than one bead, pellet, tablet, or granule per population. Graphically, an example of the presently claimed invention is shown below:



The black beads, pellets, tablets, or granules represent the population of the first active agent, the grey beads, pellets, tablets, or granules represent the population of the second active agent, and the white beads, pellets, tablets, or granules represent the population of basic substance. These three populations are all housed within a capsule.

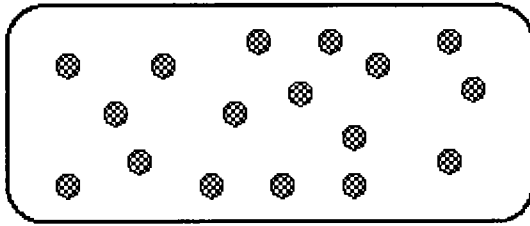
In contrast, Example VI of Phillips is directed to a tablet. The inner core of the tablet has a homogenous powder mixture of a first active agent (omeprazole) and a basic substance (sodium bicarbonate). Therefore, the population of basic substance fails to exclude the active agent, as is presently claimed. The remainder of the tablet surrounding the inner core comprises omeprazole formulated into granules. The composition of Example VI of Phillips is missing a capsule and populations of active and basic substances, wherein the basic substance excludes the active agent. Therefore, Phillips only teaches one population: the granules of omeprazole. These granules are then formulated together with a core containing a powder mixture. Additionally, the powders within the inner core of the tablet of Phillips cannot be said to be separate and distinct populations, as is presently claimed, since the basic substance and the active agent are mixed together in powder form. Graphically, the tablet of Example VI of Phillips is shown below:



Here, the black circles represent the granules of omeprazole, whereas the inner core is shown as a homogenous mixture of omeprazole (black) and basic substance (white).

Bergstrand, like Example VI of Phillips, is directed to a tablet. The tablet comprises compressed granules that are optionally enterically coated. The compressed granules comprise omeprazole mixed with a basic substance and/or coated with a

separating layer comprising a basic substance. This is completely different from the presently claimed invention and is shown graphically below:



Here, the black and white circles represent the granules of omeprazole and alkaline substance mixed together. Like Phillips, Bergstrand fails to teach or suggest a basic substance that excludes the active substance, since both are mixed together or layered on top of one another. Additionally, Bergstrand teaches only a single population with a single release rate and fails to overcome the deficiencies of Phillips with respect to the presently claimed invention.

Chen was simply cited to teach that omeprazole and an alkaline inorganic substance may be a powder or a granule, however, this basic premise fails to overcome the deficiencies of Phillips and Bergstrand with respect to the presently claimed invention.

Accordingly, for at least these reasons, Applicants submit that the claimed invention is patentable over the cited references and respectfully request that the rejection be withdrawn.

**B. Claims 2-28 and 32-45 are Allowable over Phillips in view of Bergstrand, et al., in further view of Chen**

Claims 2-28 and 32-45 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Phillips (U.S. 2002/0045646) in view of Bergstrand, et al. (U.S. Patent No. 5,817,338), in further view of Chen (U.S. 2001/0006649). Applicants respectfully traverse.

As discussed in detail above, neither Phillips nor Bergstrand, et al. nor Chen, either alone or in combination disclose, teach, or suggest all of the claimed elements. More specifically, dependent claims 2-28 and 32-45 are believed to be allowable for at least the reason that these claims depend from an allowable independent claim. *In re Fine, Minnesota Mining and Mfg.Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002). Thus, Applicants request the rejection to these claims be withdrawn.

## CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

In addition, any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. Any and all findings of inherency are traversed as not having been shown to be necessarily present. Furthermore, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known.

If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted ,

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